AMENDED IN ASSEMBLY SEPTEMBER 4, 2003

AMENDED IN ASSEMBLY AUGUST 25, 2003

AMENDED IN ASSEMBLY AUGUST 18, 2003

AMENDED IN ASSEMBLY JULY 3, 2003

AMENDED IN SENATE MAY 7, 2003

AMENDED IN SENATE APRIL 28, 2003

SENATE BILL

No. 937

Introduced by Senator Ducheny (Coauthors: Senators Bowen, Cedillo, Kuehl, and Soto)

(Coauthors: Assembly Members Chan, Diaz, Koretz, Laird, and Nunez) Bates, Chan, Diaz, Goldberg, Hancock, Koretz, Laird, Maze, Nunez, and Salinas)

February 21, 2003

An act to amend Sections 1212, 1217, 1228, and 1231 of, and to add Sections 1218.1, 1218.2, 1226.1, 1226.2, 1226.3, and 1229.1 to, the Health and Safety Code, relating to clinics.

LEGISLATIVE COUNSEL'S DIGEST

SB 937, as amended, Ducheny. Clinics: licensure and operation.

(1) Under existing law, the State Department of Health Services regulates the licensure and operation of clinics, including community clinics and primary care clinics, as defined.

Existing law requires any person, firm, association, partnership, or corporation desiring a license for a clinic or a special permit for special services to file a verified application with the department containing specified information.

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This bill would provide that an application is not required where a primary care clinic adds a service other than a special service, or modifies an existing primary care clinic site, but would require the clinic to notify the department of the changes in service or physical plant within a specified time period.

(2) Existing law authorizes the department to issue a primary care clinic license to an applicant only if it meets all requirements for licensure, except that it proposes to operate its clinic out of an existing facility that does not satisfy certain applicable building requirements for the physical plant, provided that (A) the applicant establishes that, where possible and feasible, applicable building requirements have been met, and (B) the applicant submits a specified plan of modernization. Existing law authorizes the Director of Health Services to waive building requirements for primary care clinics when certain conditions are satisfied.

This bill would make these provisions mandatory, rather than discretionary, upon the department.

This bill would authorize a primary care clinic that has held a valid, unrevoked, and unsuspended license for at least the last 5 years and that meets certain other requirements to apply for, and receive be issued, a license to establish an affiliate clinic, without the necessity of the department first conducting an initial onsite survey, in accordance with criteria set forth by the bill.

This bill would authorize 2 or more primary care clinics that are operated by a single nonprofit corporation to consolidate their administrative functions without first obtaining the approval of the department. This bill would also specify requirements applicable to a primary care clinic for the public health protection of clinic workers. The bill would void any more stringent standard imposed on a primary care clinic, that is adopted before January 1, 2004.

(3) Existing law requires every clinic to be inspected, no less than once every 2 years, in accordance with specified criteria. Existing law exempts certain facilities from this inspection requirement.

This bill would, instead, require these inspections, instead, no less than once every 3 years. The bill would add a primary care clinic with specified accreditation to the list of clinics that are exempt from this inspection requirement.

(4) Existing law requires the department to notify a clinic of all deficiencies in its compliance with the provisions relating to clinic licensure and operations.

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The California Administrative Procedure Act generally sets forth the requirements for the adoption and revision of regulations, guidelines, and criteria by state agencies.

This bill would prohibit the imposition of a notification of deficiency, fine, sanction, or denial, suspension, or revocation of licensure against a clinic for violation of a regulation, unless the regulation has been adopted pursuant to that act.

(5) Existing law requires the Office of Statewide Health Planning and Development, in consultation with the Community Clinics Advisory Committee, to prescribe minimum construction standards for adequacy and safety for the physical plant of clinics.

This bill would require that the committee consist of at least 15 members to be appointed by designated primary care clinic associations in the state, and would specify requirements for membership and meetings. It would also specify the manner in which a clinic may establish compliance with the specified standards for construction adequacy and safety.

(6) Existing law requires a clinic to comply with licensing requirements, but allows a clinic to deviate from these requirements under certain circumstances, upon written request and substantiating evidence submitted by the clinic, and with the prior written approval of the department.

This bill would state that a primary care clinic is deemed to have submitted substantiating evidence for use of alternatives to personnel requirements if the primary care clinic is in a medically underserved area or a health professional shortage area, or if the clinic serves a medically underserved population.

This bill would provide that substantiating evidence of a shortage of a specific health care professional submitted in support of a primary clinic's request for utilization of alternatives to personnel requirements contained in regulations adopted by the department may include specified documentation. In addition, where a licensee submits a single program flexibility request on behalf of more than one similarly situated primary care clinic, the bill would authorize the department to approve program flexibility requests as to each of the primary care clinics identified in the request.

(7) Under existing law, violation of the provisions relating to clinics is a misdemeanor.

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By imposing new requirements on the licensure and operation of clinics, this bill would create new crimes, thereby imposing a state-mandated local program.

(8) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. The Legislature finds and declares all of the 2 following:
 - (a) California's primary care clinics are essential partners with the state in providing a health care safety net for underserved, uninsured, and underinsured populations in a cost-effective manner.
 - (b) California's primary care clinics generate significant savings to the state and to local communities by providing primary and preventive care that responds to patients' needs before medical problems become serious or life-threatening, and by reducing the reliance of patients, including the uninsured and underinsured, on costly emergency room care, inpatient treatment and specialty care.
 - (c) Primary care clinics operate most similarly to private doctors' offices, but are required to comply with complicated, burdensome regulations more suited to hospitals, skilled nursing facilities, and other facilities intended to meet the 24-hour care needs of medically fragile patients.
- (d) The need for primary care clinics is growing dramatically 20 due to the continuing increase of uninsured and underinsured patients in California, an escalating unemployment rate, and a severely depressed economy.
 - (e) The current system of licensing primary care clinics is out of step with contemporary health care delivery systems, and results in a significant waste of taxpayer and community resources that could otherwise be devoted to patient care.

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(f) Administrative streamlining of the licensure of new and continuing primary care clinics will result in substantial cost savings to the state and improved access to health care for underserved populations.

- SEC. 2. Section 1212 of the Health and Safety Code is amended to read:
- 1212. (a) Any person, firm, association, partnership, or corporation desiring a license for a clinic or a special permit for special services under the provisions of this chapter, shall file with the department a verified application on forms prescribed and furnished by the department, containing the following:
- (1) Evidence satisfactory to the department that the applicant is of reputable and responsible character. If the applicant is a firm, association, partnership, trust, corporation, or other artificial or legal entity, like evidence shall be submitted as to the members, partners, trustees or shareholders, directors, and officers thereof and as to the person who is to be the administrator of, and exercise control, management, and direction of the clinic for which application is made.
- (2) If the applicant is a partnership, the name and principal business address of each partner, and, if any partner is a corporation, the name and principal business address of each officer and director of the corporation and name and business address of each stockholder owning 10 percent or more of the stock thereof.
- (3) If the applicant is a corporation, the name and principal business address of each officer and director of the corporation, and where the applicant is a stock corporation, the name and principal business address of each stockholder holding 10 percent or more of the applicant's stock and, where any stockholder is a corporation, the name and principal business address of each officer and director of the corporate stockholder.
- (4) Evidence satisfactory to the department of the ability of the applicant to comply with the provisions of this chapter and rules and regulations promulgated under this chapter by the department.
- (5) The name and address of the clinic, and if the applicant is a professional corporation, firm, partnership, or other form of organization, evidence that the applicant has complied with the requirements of the Business and Professions Code governing the use of fictitious names by practitioners of the healing arts.

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(6) The name and address of the professional licentiate responsible for the professional activities of the clinic and the licentiate's license number and professional experience.

- (7) The class of clinic to be operated, the character and scope of advice and treatment to be provided, and a complete description of the building, its location, facilities, equipment, apparatus, and appliances to be furnished and used in the operation of the clinic.
- (8) Sufficient operational data to allow the department to determine the class of clinic that the applicant proposes to operate and the initial license fee to be charged.
- (9) Any other information as may be required by the department for the proper administration and enforcement of this chapter, including, but not limited to, evidence that the clinic has a written policy relating to the dissemination of the following information to patients:
- (A) A summary of current state laws requiring child passenger restraint systems to be used when transporting children in motor vehicles
- (B) A listing of child passenger restraint system programs located within the county, as required by Section 27360 or 27362 of the Vehicle Code.
- (C) Information describing the risks of death or serious injury associated with the failure to utilize a child passenger restraint system.
- (10) Applicants for a license or special permit covering a project within the meaning of Section 127170 shall submit a copy of a certificate of need as required by the department.
- (b) (1) No application is required where a licensed primary care clinic adds a service that is not a special service, as defined in Section 1203, or any regulation adopted thereunder, or remodels or modifies an existing primary care clinic site. However, the clinic shall notify the department, in writing, of the change in service or physical plant no less than 60 days prior to adding the service or remodeling or modifying an existing primary care clinic site. Nothing in this subdivision shall be construed to limit the authority of the department to conduct an inspection at any time pursuant to Section 1227, in order to ensure compliance with, or to prevent a violation of, this chapter, or any regulation adopted under this chapter.

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(2) Where applicable city, county, or state law obligates the primary care clinic to obtain a building permit with respect to the remodeling or modification to be performed by the clinic, the primary care clinic shall provide a signed certification or statement as described in Section 1226.3 to the department within 60 days following completion of the remodeling or modification project covered by the building permit.

- (c) In the course of fulfilling its obligations under Section 1221.09, the department shall ensure that any application form utilized by a primary care clinic, requiring information of the type specified in paragraph (1), (4), (8), or (9) of subdivision (a), is consistent with the requirements of Section 1225, including the requirement that rules and regulations for primary care clinics be separate and distinct from the rules and regulations for specialty clinics. Nothing in this section shall be construed to require the department to issue a separate application form for primary care clinics.
- (d) The department shall ensure that any information required for submission to the department pursuant to this chapter is specifically required by state or federal statute or regulation.
- SEC. 3. Section 1217 of the Health and Safety Code is amended to read:
- 1217. (a) An applicant for a license to operate a primary care clinic, as specified in subdivision (a) of Section 1204 that meets all requirements for licensure under this chapter, except that it proposes to operate its clinic out of an existing facility that does not satisfy all of the applicable building requirements for the physical plant, other than fire and life safety requirements, shall be issued a license by the state department if both of the following requirements are met:
- (1) The applicant establishes, by evidence satisfactory to the state department, that, where possible and feasible, the applicable building requirements have been met.
- (2) The applicant submits a plan of modernization acceptable to the state department that sets forth the proposed changes to be made, during a period not to exceed three years from the date of initial licensure, to bring the applicant's facility into substantial conformance with applicable building requirements.
- (b) Failure to complete the plan of modernization as approved and within the time allowed shall constitute a basis for revocation

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or nonrenewal of the applicant's license unless the applicant earlier applies for and obtains a waiver from the department. The director shall waive building requirements for primary care clinics where he or she determines all of the following conditions are met:

- (1) That the requirements cannot be met by an applicant, or that they can be met only at an unreasonable and prohibitive cost.
- (2) That the requirements are not essential to protect the health and safety of the clinic staff or the public it serves.
- 9 (3) That the granting of the waiver applied for is in the public 10 interest.
 - SEC. 4. Section 1218.1 is added to the Health and Safety Code, to read:
 - 1218.1. (a) A primary care clinic that has held a valid, unrevoked, and unsuspended license for at least the immediately preceding five years, with no demonstrated history of repeated *or uncorrected* violations of this chapter or any regulation adopted under this chapter that present a direct risk of physical harm to patients—pose immediate jeopardy to a patient, as defined in subdivision (d), and that has no pending action to suspend or revoke its license, may file an application under this section to establish a primary care clinic at an additional site, which shall hereafter be referred to as the affiliate clinic. The department, upon receipt of the completed application, shall issue a license to approve a license for the affiliate clinic, without the necessity of first conducting an initial onsite survey, if all of the following conditions are met:
 - (1) The existing primary care clinic, which shall hereafter be referred to as the parent clinic, has submitted a completed application for licensure for the affiliate clinic and the associated application fee.
 - (2) The parent and affiliate clinics' corporate officers, as specified in Section 5213 of the Corporations Code, are the same.
 - (3) The parent and affiliate clinics are both owned and operated by the same nonprofit organization with the same board of directors.
 - (4) The parent and affiliate clinics' operational policies and procedures are substantially the same.
 - (5) The parent and affiliate clinics both follow substantially the same training, competency testing, and quality assurance standards for health care staff performing the same or similar

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functions. If an affiliate clinic will be providing primary care services different from the parent clinic, the professional director shall develop and implement training, competency testing, and quality assurance standards in conjunction with the appropriate personnel at the affiliate clinic. It shall not be necessary for the professional director to be the same for all sites.

(6)

- (4) The parent clinic has submitted evidence to the department establishing compliance with the minimum construction standards of adequacy and safety of the affiliate clinic's physical plant pursuant to subdivision (b) of Section 1226.
- (b) (1) The department shall issue a license under this section within 30 days of receipt of a completed application. *If approved, a license shall be issued within seven days of approval.*
- (2) Notwithstanding paragraph (1), if If the department determines that an applicant does not meet the conditions stated in subdivision (a), it shall identify, in writing and with particularity, the grounds for that determination, and shall instead process the application in accordance with the time specified in Section 1218.
- (c) Nothing in this section shall prohibit the department from conducting a licensing inspection at any time after receipt of the completed application.
- (d) For purposes of this section, "immediate jeopardy to a patient" means a situation in which the clinic's noncompliance with one or more requirements of licensure has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.
- SEC. 5. Section 1218.2 is added to the Health and Safety Code, to read:
- 1218.2. Notwithstanding any other provision of law, two or more primary care clinics that are operated by a single nonprofit corporation shall be entitled to consolidate their administrative functions within the State of California without first obtaining the approval of the department. The department shall have access to offsite records. Upon request for access by the department, offsite records shall either be transferred to a clinic or administrative site or be available at the offsite facility within 48 hours. The administrative functions may include, but are not limited to, all of the following: are limited to the following:
- (a) Offsite storage and maintenance of patient medical records that have been inactive for at least three years.

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(b) Offsite storage and maintenance of personnel records, except that copies of specific records documenting the employees' date of hire, general qualifications, proof of current licensure if applicable, training, and annual health checks shall be kept at the site at which the employee provides all or a majority of his or her services.

- (c) Billing and related financial functions.
- (d) Purchasing functions.
- SEC. 6. Section 1226.1 is added to the Health and Safety 10 Code, to read:
 - 1226.1. (a) A primary care clinic shall comply with the following requirements regarding health examinations and other public health protections for individuals working in a primary care clinic:
 - (1) An employee working in a primary care clinic who has direct contact with patients shall have a health examination within six months prior to employment or within 15 days after employment. Each examination shall include a medical history and physical evaluation. A written examination report, signed by the person performing the examination, shall verify that the employee is able to perform his or her assigned duties.
 - (2) At the time of employment, testing for tuberculosis shall consist of a purified protein derivative intermediate strength intradermal skin test. If a positive reaction is obtained from the skin test, the employee shall be referred to a physician to determine if a chest X-ray is necessary. Annual examinations shall be performed only when medically indicated.
 - (3) The clinic shall maintain a health record for each employee that includes reports of all employment-related health examinations. These records shall be kept for a minimum of three years following termination of employment.
 - (4) An employee known to have or exhibiting signs or symptoms of a communicable disease shall not be permitted to work until he or she submits a physician's certification that the employee is sufficiently free of the communicable disease to return to his or her assigned duties.
 - (b) Any regulation adopted before January 1, 2004, that imposes a standard on a primary care clinic that is more stringent than described in this section is void.

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SEC. 7. Section 1226.2 is added to the Health and Safety Code, to read:

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1226.2. The Community Clinics Advisory Committee provided for in subdivision (b) of Section 1226 shall meet on an ad hoc basis and shall be comprised of at least 15 individuals who are employed by, or under contract to provide service to, a community clinic on a full-time basis, either directly or as a representative of a clinic association. Members of the committee shall be appointed by the three statewide primary care clinic associations in California that represent the greatest number of community or free clinic sites.

SEC. 8. Section 1226.3 is added to the Health and Safety Code, to read:

1226.3. A primary care clinic may establish compliance with the minimum construction standards of adequacy and safety for the physical plant described in subdivision (b) of Section 1226 by submitting a written certification, as described in Section 5536.26 of the Business and Professions Code, from a licensed architect or a written statement from a local building department that the applicable construction, remodeling, alteration, or other applicable modification of the physical plant is in compliance with these standards. No particular form of certification or statement shall be required by the department. Any form of statement utilized by a city or county building department, or certification by a licensed architect, indicating that the premises conform to the requirements of the California Building Standards Code, shall be accepted by the department as sufficient proof of compliance. Enforcement of compliance with applicable provisions of the California Building Standards Code, pursuant to subdivision (b) of Section 1226, shall be within the exclusive jurisdiction of the local building department.

SEC. 9. Section 1228 of the Health and Safety Code is amended to read:

1228. (a) Except as provided in subdivision (c), every clinic for which a license or special permit has been issued shall be periodically inspected. The frequency of inspections shall depend upon the type and complexity of the clinic or special service to be inspected. Inspections shall be conducted no less often than once every three years and as often as necessary to ensure the quality of care being provided.

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(b) (1) During inspections, representatives of the department shall offer any advice and assistance to the clinic as they deem appropriate. The department may contract with local health departments for the assumption of any of the department's responsibilities under this chapter. In exercising this authority, the local health department shall conform to the requirements of this chapter and to the rules, regulations, and standards of the department.

- (2) The department shall reimburse local health departments for services performed pursuant to this section, and these payments shall not exceed actual cost. Reports of each inspection shall be prepared by the representative conducting it upon forms prepared and furnished by the department and filed with the department.
 - (c) This section shall not apply to any of the following:
 - (1) A rural health clinic.

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- (2) A primary care clinic accredited by the Joint Commission 18 on Accreditation of Healthcare Organizations (JCAHO), the Accreditation Association for Ambulatory Health Care (AAAHC), or any other accrediting organization recognized by the department.
 - (3) An ambulatory surgical center.
 - (4) An end stage renal disease facility.
 - (5) A comprehensive outpatient rehabilitation facility that is certified to participate either in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 et seq.) of the federal Social Security Act, or the medicaid program under Title XIX (42 U.S.C. Sec. 1396 et seq.) of the federal Social Security Act, or both.
 - (d) Notwithstanding paragraph (2) of subdivision (c), the department shall retain the authority to inspect a primary care clinic pursuant to Section 1227, or as necessary to ensure the quality of care being provided.
 - SEC. 10. Section 1229.1 is added to the Health and Safety Code, to read:
- 1229.1. No notification of deficiency, civil or criminal penalty, fine, sanction, or denial, suspension, or revocation of 36 licensure, may be imposed against a primary care clinic, or any person acting on behalf of the clinic, for a violation of a regulation, as defined in Section 11342.600 of the Government Code, including every rule, regulation, order, or standard of general

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application, or the amendment, supplement, or revision of any rule, regulation, order, or standard adopted by a state agency to implement, interpret, or make specific the law enforced or administered by it, or to govern its procedure, unless the regulation has been adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 11. Section 1231 of the Health and Safety Code is amended to read:

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1231. (a) All clinics shall maintain compliance with the licensing requirements. These requirements shall not, however, prohibit the use of alternate concepts, methods, procedures, techniques, space, equipment, personnel qualifications, or the conducting of pilot projects, provided these exceptions are carried out with provision for safe and adequate patient care and with prior written approval of the department. A written request and substantiating evidence supporting the request shall be submitted by the applicant or licensee to the state department. Where a licensee submits a single program flexibility request and substantiating evidence on behalf of more than one similarly situated primary care clinic, the department may approve the program flexibility request as to each of the primary care clinics identified in the request. The department shall approve or deny any request within 60 days of submission. This approval shall be in writing and shall provide for the terms and conditions under which the exception is granted. A denial shall be in writing and shall specify the basis therefor.

(b) A primary care clinic shall be deemed to have submitted sufficient substantiating evidence of a shortage of a specific health care—professional—supporting—a request for utilization—of alternatives to personnel requirements contained in regulations adopted under this chapter if the clinic is in a geographic area that

(b) Substantiating evidence of a shortage of a specific health care professional that is submitted in support of a request for utilization of alternatives to personnel requirements contained in regulations adopted under this chapter may include documentation that the clinic is located in a geographic area that is either deemed under federal law, or designated by the Office of Statewide Health Planning and Development, as a medically

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underserved area, a health professional shortage area, or as serving, in whole or in part, a medically underserved population.

- (c) If after investigation the department determines that a clinic granted a waiver pursuant to this section is operating in a manner contrary to the terms or conditions of the waiver, the director shall immediately revoke the waiver as to that clinic site.
- SEC. 12. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the